General

Guideline Title

Management of adult testicular germ cell tumours. A national clinical guideline.

Bibliographic Source(s)

Scottish Intercollegiate Guidelines Network (SIGN). Management of adult testicular germ cell tumours. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2011 Mar. 63 p. (SIGN publication; no. 124). [152 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Management of adult testicular germ cell tumours. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 1998 Sep. 39 p. (SIGN publication; no. 28). [87 references]

Recommendations

Major Recommendations

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.

The strength of recommendation grading (A-D) and level of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Presentation and Referral

D - Those patients suspected of harbouring a testicular malignancy, i.e., a lump in the testis, doubtful epididymo-orchitis or orchitis not resolving within two to three weeks, should be referred urgently for urological assessment.

Tumour Markers

C - Measurement of serum alpha-fetoprotein (AFP) and human chorionic gonadotropin (HCG) is essential in the follow up of patients with non-seminomatous germ cell tumours.

Primary Management

Preoperative Investigations

D - Preoperative investigations should include assay of AFP, HCG, and lactate dehydrogenase (LDH), bilateral testicular ultrasound, and a chest X-ray.

Primary Surgical Management

Inguinal Approach

D - Where possible an inguinal orchidectomy should be performed.

Testicular Prostheses

D - A testicular prosthesis should be offered to all patients.

Fertility Issues

D - When appropriate, sperm storage should be offered to men who may require chemotherapy or radiotherapy.

Referral to Oncology

D - Following confirmation of a germ cell tumour, all patients should be referred to a specialist centre for the management of testicular tumours.

Management of the Contralateral Testis

Diagnosis of Carcinoma in Situ (CIS)

D - Patients with a testicular cancer who are 30 years old or less and have a small (<12 ml) contralateral testis should be considered for biopsy of the contralateral testis to diagnose CIS. If CIS is identified subsequent management should be in a specialist centre.

Management of CIS

D - Patients with biopsy-proven CIS of the contralateral testis should have the options of surveillance, prophylactic orchidectomy and adjuvant radiotherapy discussed with them. Where radiotherapy is given, a dose of 20 Gy in 10 fractions over two weeks is adequate to eradicate CIS and testosterone replacement may not be necessary.

Clinical Staging

Staging Systems

D - Marker concentrations should be used along with imaging techniques to allocate a prognostic group.

Radiological Staging

D - Contrast-enhanced computed tomography (CECT) scanning of the thorax, abdomen and pelvis is an essential part of the staging of all germ cell tumours.

Management of Stage 1 Disease

Management of Stage 1 Seminoma

C - Patients with stage I seminoma should have the advantages and disadvantages of the various post-orchidectomy management options discussed with them, including surveillance, single-dose adjuvant carboplatin and adjuvant radiotherapy.

Active Surveillance

B - In patients with stage I seminoma post-orchidectomy, active surveillance may be considered as a management option.

Adjuvant Radiotherapy

A - In patients with stage I seminoma who have undergone no previous inguinoscrotal surgery and who are to receive adjuvant radiotherapy following orchidectomy, the volume should be limited to the para-aortic nodal strip.

D - In patients with stage I seminoma who have undergone previous inguinoscrotal surgery and who are to receive adjuvant radiotherapy following orchidectomy, the para-aortic nodal strip volume should be extended to include the ipsilateral pelvic nodes ('dog-leg radiotherapy').

A - In patients with stage I seminoma who are to receive adjuvant 'dog-leg' or para-aortic strip radiotherapy, a dose of 20 Gy in ten fractions over

two weeks should be prescribed to the ICRU reference point.

C - The potential risk of second malignant neoplasms should be outlined to patients where adjuvant radiotherapy is being considered.

Adjuvant Chemotherapy

A - In post-orchidectomy patients with stage I seminoma, adjuvant carboplatin chemotherapy may be considered as a management option.

Management of Stage 1 Non-Seminomatous Germ Cell Tumours (NSGCTs) and Mixed Seminoma/NSGCT

C - Patients with stage I NSGCTs or mixed seminoma/NSGCT of the testis with no high-risk features should be managed by surveillance following inguinal orchidectomy.

B - In low-risk patients under surveillance, CT scanning at three and 12 months postorchidectomy is recommended.

D - A pelvic CT scan is only indicated where there are known risk factors for pelvic disease.

Adjunctive Chemotherapy

D - Two courses of adjuvant BEP chemotherapy should be offered to patients with stage I NSGCT or mixed seminoma/NSGCT of the testis following inguinal orchidectomy if high-risk features are present (blood vessel and/or lymphatic invasion) or if the patient is unable or unwilling to comply with a policy of surveillance.

Management of Metastatic Disease

Management of Metastatic Seminoma

Stage IIA and IIB Seminoma

D - Sequential chemotherapy and radiotherapy can be considered as an alternative to radiotherapy alone in stage IIB.

Stage IIC and IID Seminoma

C - For patients with stage IIC or IID seminoma, chemotherapy is the recommended initial treatment.

C - Scheduling of chemotherapy is similar to that used for NSGCTs, although the risks of bleomycin pulmonary toxicity may be higher in this generally older age group and bleomycin omission should be considered.

Stage III and IV Seminoma

C - Patients with stage III and IV seminoma should be treated with cisplatin-based chemotherapy.

B - In patients with stage III and IV seminoma carboplatin should only be used as an alternative to cisplatin in exceptional circumstances.

Management of Non-seminomatous Germ Cell Tumours

Management of Good Prognosis Disease

A - Patients with a good prognosis metastatic non-seminomatous germ cell tumour should receive three cycles of BEP chemotherapy in either a 3-day or 5-day schedule.

Cisplatin and Carboplatin

A - In patients with good prognosis metastatic non-seminomatous germ cell tumours carboplatin should only be given in circumstances in which cisplatin is contraindicated.

Bleomycin

A - Patients with good prognosis metastatic non-seminomatous germ cell tumour and in whom bleomycin is contraindicated should receive four cycles of EP chemotherapy (with 500 mg/m^2 etoposide and 100 mg/m^2 cisplatin per cycle).

D - Chemotherapy should only be given in a specialist centre and overseen by a clinician experienced in the management of germ cell tumours.

Management of Patients with Intermediate and Poor Prognosis Non-seminomatous Germ Cell Tumours

D - Patients with adverse prognostic factors should be treated in specialist centres. Where possible, patients should be entered into well designed multicentre studies to define the optimal treatment for this group.

B - Outwith the trial setting standard initial chemotherapy for patients with intermediate and poor-risk germ cell tumours is four courses of 5-day BEP.

Management of Residual Masses After Chemotherapy

Surgery

NSGCT

D - Patients with NSGCT who have residual masses after chemotherapy and whose markers have normalized should be treated by complete excision.

D - If the primary testicular tumour has not already been removed, an orchidectomy should be performed at the same time as retroperitoneal lymph node dissection.

Radiotherapy

D - Patients with seminoma who have residual masses following chemotherapy can generally be managed by a policy of observation rather than radiotherapy.

Treatment of Relapsed Disease

D - Patients with testicular germ cell cancer who relapse after first line cisplatin based chemotherapy should be managed in specialised centres.

D - The International Prognostic Factors Study Group's model should be applied to guide prognostic information for patients who relapse after first line platinum based chemotherapy.

C - Due to the low survival predicted for the Beyer poor prognosis group (*score >2*) such patients should not be subjected to high-dose chemotherapy. Those with intermediate and good Beyer prognostic score (*0 to 2*) may be considered for high-dose chemotherapy.

B - High-dose chemotherapy is not routinely recommended as salvage therapy for germ cell cancer patients who relapse after standard platinum based chemotherapy.

Late Toxicity

Cardiovascular Late Effects

Individual Management Strategies

C - Survivors of testicular cancer should be advised not to smoke.

Post-Treatment Follow Up

Follow-up Strategies for Stage 1 Seminoma

Adjuvant Carboplatin

B - Patients who undergo surveillance or adjuvant therapy for stage I seminoma should be followed up according to protocols which take into account the likely site and timing of first relapse to define the frequency of clinic visits, blood tests and radiology investigations. This should include cross-sectional imaging of the abdomen in patients under surveillance and after adjuvant carboplatin, and chest imaging in all patients. Cross-sectional imaging of the pelvis may also be indicated in selected patients (e.g., after para-aortic radiotherapy alone, or where the risk of pelvic nodal disease is considered to be elevated).

Pathology of Testicular Germ Cell Tumours

Histological Examination of Testicular Tumours

C - The presence or absence of blood or lymphatic vascular invasion should be specified.

Definitions:

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1–: Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies; high quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2–: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g., case reports, case series

4: Expert opinion

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review, or RCT rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Testicular germ cell tumours:

- Seminoma
- Non-seminomatous germ cell tumours (NSGCTs)
- Mixed seminoma/NSGCT

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Nursing

Oncology

Pathology

Radiation Oncology

Radiology

Urology

Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

Guideline Objective(s)

To provide recommendations based on current evidence for best practice in the management of testicular cancer

Target Population

Adult men with testicular germ cell tumours

Note: This guideline excludes the management of germ cell testicular tumours in children, germ cell tumours in women and extragonadal tumours.

Interventions and Practices Considered

Diagnosis/Initial Management

1. Preoperative measurements of alpha-fetoprotein (AFP), human chorionic gonadotrophin (HCG), and lactate dehydrogenase (LDH); bilateral testicular ultrasound and chest x-ray
2. Inguinal orchidectomy with or without testicular prostheses
3. Semen analysis and sperm storage, when appropriate
4. Clinical specialist nursing care
5. Biopsy of contralateral testis
6. Surveillance, prophylactic orchidectomy or adjuvant radiotherapy for carcinoma in situ (CIS)
7. Contrast-enhanced computed tomography (CECT) scanning of the thorax, abdomen and pelvis
8. Clinical staging using the International Germ Cell Consensus Classification (IGCCC)

Stage-Specific Management/Treatment

Stage I Seminoma

1. Active surveillance post-orchidectomy
2. Single-dose adjuvant carboplatin
3. Adjuvant radiotherapy
4. Patient counseling on management options

Stage I Non-Seminomatous Germ Cell Tumour (NSGCT) and Mixed NSGCT/Seminoma

1. Surveillance post-orchidectomy
2. CT scan at 3 and 12 months in low-risk patients
3. Pelvic CT if at risk for pelvic disease
4. Adjuvant chemotherapy (bleomycin-etoposide-cisplatin [BEP]) for high-risk patient or patients who cannot comply with surveillance

Metastatic Seminoma

1. Radiotherapy alone for stage IIa and IIB disease
2. Sequential chemotherapy and radiotherapy for stage IIA and IIB disease
3. Chemotherapy with BEP or etoposide/cisplatin (EP) for stage IIC and IID disease
4. Cisplatin-based chemotherapy for stage III and IV seminoma (carboplatin may be substituted in exceptional circumstances)

Metastatic NSGCT

1. Chemotherapy with BEP or EP in good prognosis cases (carboplatin may be substituted for cisplatin in exceptional circumstances)
2. Clinical trial or BEP for poor prognosis patients
3. Treatment in a specialist centre for poor prognosis patients

Residual Masses After Chemotherapy

1. Complete excision of residual mass and associated abnormal tissue for NSGCT
2. If not done previously, orchidectomy with removal of retroperitoneal lymph nodes for NSGCT
3. Observation for patients with seminoma

Relapsed Disease

1. Referral to specialist centre for chemotherapy trials
2. Reassessment of prognosis using the International Prognostic Factors Study Group model
3. High-dose chemotherapy for patients with intermediate prognosis (not recommended for patients with poor prognosis or who previously had standard platinum based chemotherapy)

Follow-up

1. Advice not to smoke
2. Appropriate imaging and investigation for patients under surveillance or adjuvant therapy

Major Outcomes Considered

- Sensitivity and specificity of diagnostic instruments
- Relapse/progression rates
- Response rates
- Treatment/disease related morbidity
- Survival rates

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Systematic Literature Review

The evidence base for this guideline was synthesised in accordance with the Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using an explicit search strategy devised by a SIGN Information Officer. Databases searched include Medline, Embase, CINAHL and the Cochrane Library. The year range covered was 1998-2010. The main searches were supplemented by material identified by individual members of the development group. Each of the selected papers was evaluated by two members of the group using standard SIGN methodological checklists before conclusions were considered as evidence.

Literature Search for Patient Issues

At the start of the guideline development process, a SIGN Information Officer conducted a literature search for qualitative and quantitative studies that addressed patient issues of relevance to management of testicular germ cell tumours. Databases searched include Medline, Embase, CINAHL and PsycINFO, and the results were summarized and presented to the guideline development group.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1–: Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2–: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal<

3: Non-analytic studies, e.g., case reports, case series

4: Expert opinion

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports.

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. The Scottish Intercollegiate Guidelines Network (SIGN) has based its assessments on the Method for Evaluating Research and Guideline Evidence (MERGE) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use.

The assessment process inevitably involves a degree of subjective judgment. The extent to which a study meets a particular criterion - e.g., an acceptable level of loss to follow up - and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two group members. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer or an experienced member of SIGN Executive staff will arbitrate to reach an agreed quality assessment.

Evidence Tables

Evidence tables are compiled by SIGN executive staff based on the quality assessments of individual studies provided by guideline development group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site .

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Synthesising the Evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgment is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgment on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Considered Judgment

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, the Scottish Intercollegiate Guideline Network (SIGN) has introduced the concept of considered judgment.

Under the heading of considered judgment, guideline development groups summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- External validity (generalisability) of study findings
- Directness of application to the target population for the guideline
- Any evidence of potential harms associated with implementation of a recommendation
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them in accordance with the recommendation)
- Whether, and to what extent, any equality groups may be particularly advantaged or disadvantaged by the recommendations made
- Implementability (i.e., how practical it would be for the NHS in Scotland to implement the recommendation)

The group are finally asked to summarize its view on all of these issues, both the quality of the evidence and its potential impact, before making a graded recommendation. This summary should be succinct, and taken together with its views of the level of evidence represent the first draft of the text that will appear in the guideline immediately before a graded recommendation.

Additional detail about SIGN's process for formulating guideline recommendations is provided in Section 6 of the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN Web site .

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review, or randomized controlled trial (RCT) rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development.

Peer Review

All SIGN guidelines are reviewed in draft form by independent expert referees, who are asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. A number of general practitioners (GPs) and other primary care practitioners also provide comments on the guideline from the primary care perspective, concentrating particularly on the clarity of the recommendations and their assessment of the usefulness of the guideline as a working tool for the primary care team. The draft is also sent to at least two lay reviewers in order to obtain comments from the patient's perspective.

It should be noted that all reviewers are invited to comment as individuals, not as representatives of any particular organization or group. Corporate interests, whether commercial, professional, or societal have an opportunity to make representations at the national meeting stage where they can send representatives to the meeting or provide comment on the draft produced for that meeting. Peer reviewers are asked to complete a declaration of interests form.

The comments received from peer reviewers and others are carefully tabulated and discussed with the Chair and with the guideline development group. Each point must be addressed and any changes to the guideline as a result noted or, if no change is made, the reasons for this recorded.

As a final quality control check prior to publication, the guideline and the summary of peer reviewers' comments are reviewed by the SIGN Editorial Group for that guideline to ensure that each point has been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. Each member of the guideline development group is then asked formally to approve the final guideline for publication.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of patients with adult testicular germ cell tumours

Potential Harms

General

- Chemotherapy and radiotherapy may result in infertility.
- Despite good treatment outcomes and excellent prognosis, there remains a significant risk of psychological morbidity associated with the complex physical and emotional effects of the disease and treatments.

Chemotherapy

- *Cisplatin*: The side effects of cisplatin comprise a significant component of both the early and late toxicity of the bleomycin-etoposide-cisplatin (BEP) regimen. These toxicities include renal impairment, neuropathy, high tone hearing loss and additionally, in the short term, severe gastrointestinal toxicity. The amelioration of renal damage by the use of intensive hydration techniques is important although this adds to the inpatient stay for continuous intravenous infusion therapy. However, the renal damage of cisplatin even with intensive hydration techniques tends to cause loss of approximately 18% of the patient's glomerular filtration capacity and, although this causes little immediate problem, for successfully treated patients who reach their fifth and sixth decades of life there may be a considerable burden, especially an increased risk of hypertension.
- *Carboplatin*: Carboplatin causes little renal toxicity at conventional dosage and does not cause significant neurotoxicity or ototoxicity. As a result it is an attractive candidate as an alternative to cisplatin in the management of patients with good prognosis disease. Trials comparing carboplatin with cisplatin in this group of patients have been undertaken to assess if efficacy can be maintained with a reduction in toxicity. These trials found that substitution of cisplatin with carboplatin results in either no difference or inferior response rates, relapse-free survival and overall survival.
- *Bleomycin*: Bleomycin treatment can cause a number of side effects, including skin rashes and allergic reactions, but pneumonitis is the most serious because of the potential for fatal pulmonary toxicity in 1% of patients. Patients with impaired renal function are at increased risk of developing pneumonitis, especially in those aged >40 years, with stage IV disease or with cumulative bleomycin dose greater than 300 mg.

Surgery

- Surgery for seminoma (residual masses after chemotherapy): Resection of seminoma is difficult and potentially dangerous due to lack of clear tissue planes and tumour infiltration beyond resection margins, and is limited to exceptional cases.
- Surgery for teratoma (residual masses after chemotherapy): Surgical clearance of the retroperitoneal nodes or complete para-aortic lymphadenectomy can be performed but with an increased risk of retrograde ejaculation.

Late Toxicity

There are well documented short, medium and long term effects of treatment such as neurotoxicity, nephrotoxicity, pulmonary toxicity and androgen deficiency. There is also an emerging body of evidence of very late toxicity occurring well beyond the time most people are discharged. The most serious of these late effects, with the largest volume of evidence, pertains to the risk of second cancers and cardiovascular (CV) events. See the original guideline document for details.

Contraindications

Contraindications

- Computed tomography (CT) scanning may be contraindicated in cases of allergy to contrast media.
- Patients with impaired renal function are at increased risk of developing pneumonitis, especially in those aged >40 years, with stage IV disease or with cumulative bleomycin dose greater than 300 mg.

Qualifying Statements

Qualifying Statements

This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgment must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgment should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is, however, advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

Prescribing of Licensed Medicines Outwith Their Marketing Authorisation

Recommendations within this guideline are based on the best clinical evidence. Some recommendations may be for medicines prescribed outwith the marketing authorisation (product license). This is known as 'off label' use. It is not unusual for medicines to be prescribed outwith their product license and this can be necessary for a variety of reasons.

Generally the unlicensed use of medicines becomes necessary if the clinical need cannot be met by licensed medicines; such use should be supported by appropriate evidence and experience.

Medicines may be prescribed outwith their product license in the following circumstances:

- For an indication not specified within the marketing authorisation
- For administration via a different route
- For administration of a different dose

Prescribing medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescribers' professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.

Any practitioner following a Scottish Intercollegiate Guideline Network (SIGN) recommendation and prescribing a licensed medicine outwith the product license needs to be aware that they are responsible for this decision, and in the event of adverse outcomes, may be required to justify the actions that they have taken.

Prior to prescribing, the licensing status of a medication should be checked in the current version of the British National Formulary (BNF).

Implementation of the Guideline

Description of Implementation Strategy

Implementation of national clinical guidelines is the responsibility of each NHS Board and is an essential part of clinical governance. Mechanisms should be in place to review care provided against the guideline recommendations. The reasons for any differences should be assessed and addressed where appropriate. Local arrangements should then be made to implement the national guideline in individual hospitals, units and practices.

Auditing Current Practice

A first step in implementing a clinical practice guideline is to gain an understanding of current clinical practice. Audit tools designed around guideline recommendations can assist in this process. Audit tools should be comprehensive but not time consuming to use. Successful implementation and audit of guideline recommendations requires good communication between staff and multidisciplinary team working.

The guideline development group has identified the following as key points to audit to assist with the implementation of this guideline:

- Scotland-wide audit of survivors of testicular cancer linked to hospital admissions and death registry for ICD-10 coded cardiovascular disease for patients diagnosed 1980-1990, 1990-2000 and 2000-2010.
- Survey of survivors of testicular cancer and their GPs regarding information needs for long term follow up.
- Audit of long term side effects of treatment for germ cell tumours.
- Audits of compliance with local imaging and staging protocols.

Core data for subsequent audit should include an assessment of:

- Any delay in patients presenting to a doctor
- Timing from presentation to referral and further investigation
- Preoperative investigations
- Number of patients offered and receiving a testicular prosthesis
- Number of patients offered and having sperm stored
- Time from surgery to seeing oncologist
- Number of patients having biopsy of contralateral testis
- Adequacy of and time for completion of staging
- Details of radiotherapeutic management
- Details of chemotherapeutic management

- Details of further surgical management
- Details of timing of clinic follow up and subsequent investigations
- Details of toxicity of treatment
- Survival and relapse details

Resource Implications of Key Recommendations

No resource implications for key recommendations were identified.

Implementation Tools

Audit Criteria/Indicators

Patient Resources

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Scottish Intercollegiate Guidelines Network (SIGN). Management of adult testicular germ cell tumours. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2011 Mar. 63 p. (SIGN publication; no. 124). [152 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1998 Sep (revised 2011 Mar)

Guideline Developer(s)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

Source(s) of Funding

Scottish Executive Health Department

Guideline Committee

Not stated

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Declarations of interests were made by all members of the guideline development group. Further details are available from the Scottish Intercollegiate Guidelines Network (SIGN) Executive.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Management of adult testicular germ cell tumours. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 1998 Sep. 39 p. (SIGN publication; no. 28). [87 references]

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site .

Availability of Companion Documents

The following is available:

- Quick reference guide: Management of adult testicular germ cell tumours. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2011 Mar 2 p. Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site .
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2011 Nov. 111 p. (SIGN publication; no. 50). Electronic copies available from the SIGN Web site .

- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research and Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site .

Section 15 of the original guideline document also contains key points to audit.

Patient Resources

Section 14 of the original guideline document contains patient information.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This summary was completed by ECRI on February 6, 2002. The information was verified by the guideline developer as of April 9, 2002. This NGC summary was updated by ECRI Institute on February 17, 2012. The updated information was verified by the guideline developer on March 7, 2012.

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